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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,415

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Piero Petrini

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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

03/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,415	Applicant(s) PETRINI ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 14, 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121 (d) are required in this application because a) the lines, numbers and letters are not uniform clean and well defined (of a generally poor quality) (37 CFR 1.84(I)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 21, lines 2-3, applicant positively recites part of a human, i.e. "projections towards the corresponding laminar arch". Thus claim 21 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 25-26, 29-32** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25-26, 29-32 recite the limitation "plates". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

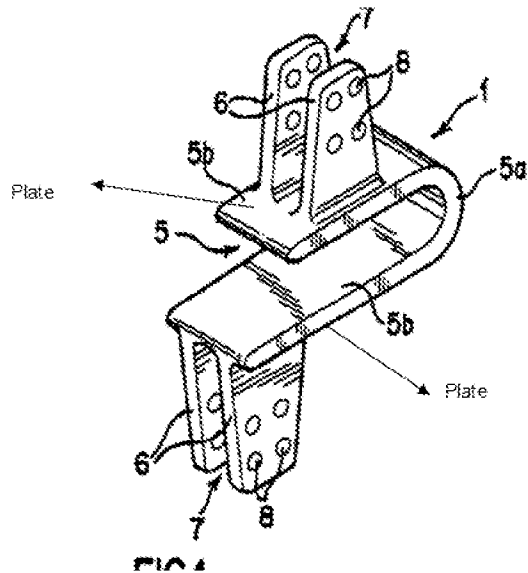
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 17-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Samani US 5,645,599.

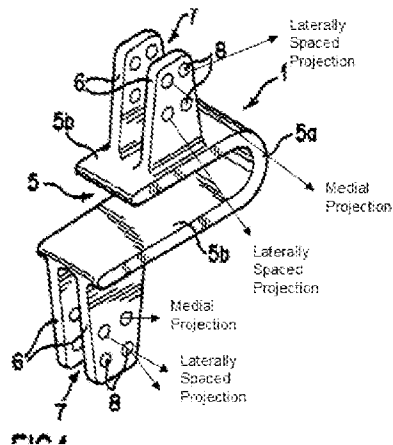
Regarding **Claim 17-19**, Samani discloses an intervertebral prosthesis comprising an elastic body (#5), securing means in the form of plates, where the plate is

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substantially rigid (as seen in Fig below and see Col 3 lines 37-41, where the body #5 is elastic and Col 3 lines 43-44, where the plates are substantially rigid).

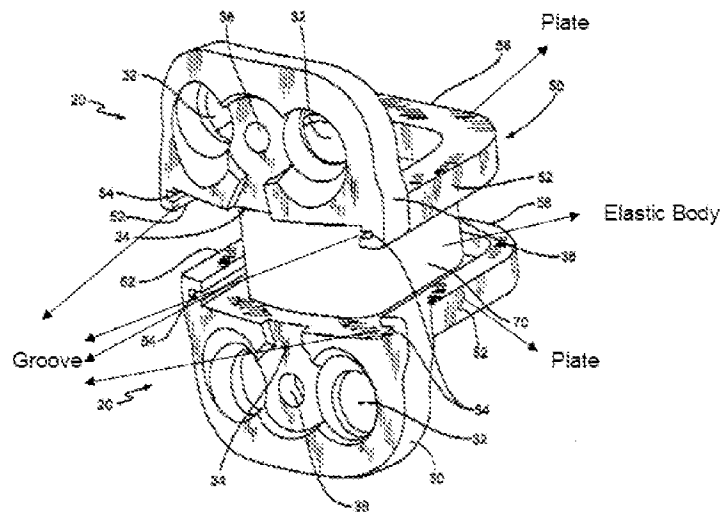


Regarding **Claims 20-23**, Samani discloses three projections, where there are two laterally spaced apart projections and a median projection (as seen in Fig below and Col 3 lines 54-58, where the holes #8 are for projections/screws), where the median projection is sufficiently thin that it would not compress the spinal cord (see Fig below and Col 3 lines 54-58, where projection would engage bone not compress the spinal cord).



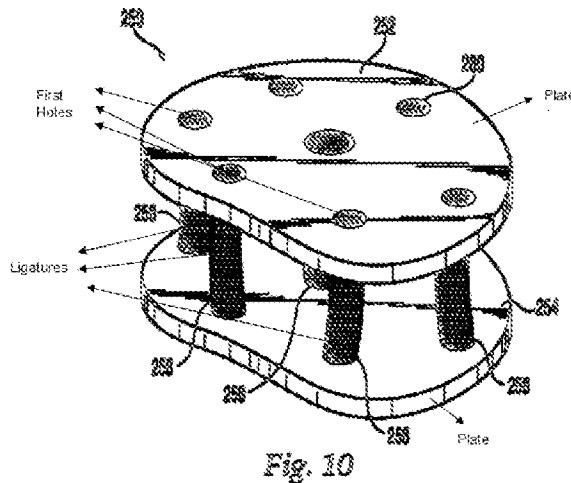
8. **Claims 17-19, 26-27** are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al US 2004/0068318.

Coates discloses an intervertebral prosthesis comprising an elastic body, means for securing the elastic body via anchoring plates, where the plates are rigid and where the plates have a surface groove, where the grooves are parallel to each other (as seen in Fig below and see paragraph 14, 19, where the body is elastic and see paragraph 17 where the plates are rigid).



9. **Claims 17-19, 24-25** are rejected under 35 U.S.C. 102(e) as being anticipated by Coppes et al US 2005/0197702.

Coppes discloses an intervertebral prosthesis comprising an elastic body, means for securing the elastic body via anchoring plates, where the plates are rigid, and connections means, including ligatures, passing through each through a first hole in the plates and a second hole in the elastic body (as seen in Fig below and see paragraph 92, where the elastic membrane/body is discussed but not shown in the Fig below, where the ligatures would pass through second holes in the elastic body, and see Fig below, where only the first holes are shown in one plate, where the other plate would also have corresponding first holes for the ligatures).



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

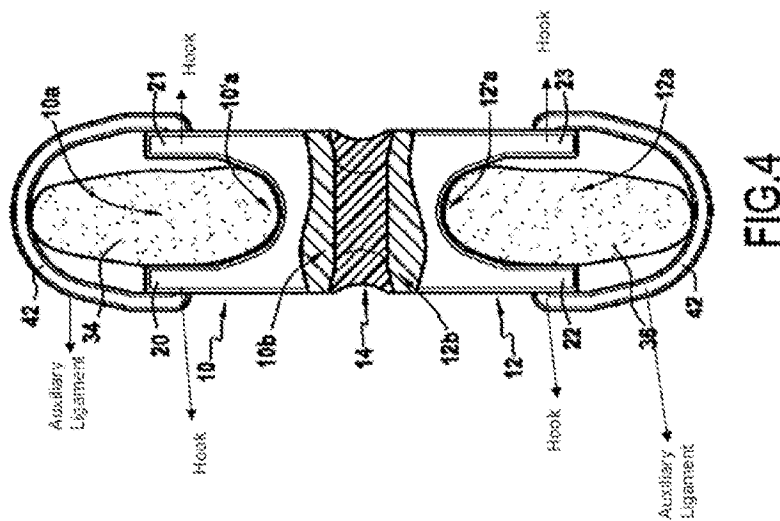
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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claims 28-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Samani US 5,645,599 in view of Le Couedic et al WO/2002/003882 (reference is made to US 2004/0106995, which is the English equivalent to LeCouedic et al) and Senegas WO/2001/28442 (reference is made to US 6,761,720m which is the English equivalent to Senegas).

Samani discloses the claimed invention as disclosed above, where each plate includes two lateral hooks (#8) for engagement with bone via bone screws (see Col 3 lines 55-57) but does not specifically disclose the hooks are used for engaging an auxiliary ligament.

However, Le Couedic teaches the use of anchors as well as auxiliary ligaments to secure and implant in place (see Fig below and see also Fig 3, where anchors are used).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthesis of Samani to use an auxiliary ligament instead of bone anchors to secure the prosthesis as taught by Le Coudedic because it is a simple substitution of one known type of anchoring element for another to obtain predictable results of securing an implant in place (see paragraph 52).

However, Le Coudedic does not specifically disclose the use of a single auxiliary ligament. However, Senegas discloses a similar device with the use of a single auxiliary element (#4" as seen in Figs 3-4).

It would have also been obvious to one having ordinary skill in the art to modify the auxiliary ligament of Le Coudedic to use a single auxiliary element as taught by Senegas because it applies a known technique to a known device ready for improvement to yield predictable results of securing an implant around bone (see Col 3 lines 54-58), where the prosthesis can simultaneously be tightened around the bone.

Response to Arguments

14. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733